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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,323	09/28/2000	Henry A. Lardy	HOLISED.063A	2363

26551 7590 02/05/2002

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 02/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/2/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-10 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-10 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

09/675,323

Am 1627

Claims 1-10 have been examined only with respect to the elected species.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of an androgen responsive disease, does not reasonably provide enablement for preventing an androgen responsive disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification fails to provide any evidence that the claimed methods are effective in preventing an androgen responsive disease.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is encompassed by the term "prevent" i.e. whether prevention is achieved for a period of days, months, years or whether permanent prevention is achieved. It is improper to use the terms "comprise" and "comprises" (claims 1 and 8-9) with respect to a compound claim because it leaves the structural formula of the compound open-ended.

Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The terminology "a compound or genus of compounds named in compound groups 1 through 13-11 as disclosed herein" renders claim 3 indefinite since it is not clear what compounds are encompassed by said terminology.

It is not clear what is encompassed by the terminology "second therapy" (claim 6).

The term "optionally" renders claim 7 indefinite.

The terminology "selected from" (claims 8-9) is an improper markush terminology. Such terminology as "selected from the group consisting of" can be used to overcome the rejection. With respect to the markush terminology "selected from the group consisting of", it is improper to use the term "or" (claims 8-9) instead of the term "and" between the last two species of the markush group.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Neumann (U.S. Patent No. 4,310,523).

Neumann discloses a method of administering a composition comprising an anti-estrogen

and an anti-androgen for the treatment or prophylaxis of an androgen responsive disease.

Therefore, the claimed methods are anticipated by Neumann.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (Proc. Natl. Acad. Sci. USA Vol. 96, Issue 20, 11173-11177, September 28, 1999), Miyamoto et al (Proc. Natl. Acad. Sci. USA Vol. 95, Issue 19, 11083-11099, September 15, 1998 or Neumann (U.S. Patent 4,310,523).

Chang et al disclose that 1,3,5(10)-estratriene-17-ethynyl-3,17-diol possess androgenic activity.

Miyamoto et al disclose that Adiol possess androgenic activity.

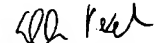
Neumann discloses administration of a combination of an anti-estrogen and an anti-androgen to a subject (column 2).

Therefore, a person having ordinary skill in the art at the time the instant invention was made would be motivated to use the compounds disclosed by Chang et al or Miyamoto et al or the composition disclosed by Neumann to treat an androgen responsive disease. The claimed methods are deemed prima facie obvious over Chang et al or Miyamoto et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peslev whose telephone number is (703) 308-4616. The examiner can normally be reached on weekdays from 8.30 a.m. to 5.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


ELLI PESELEV
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GROUP 1800